UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,231	08/08/2001	Patricia G. Spear	7853-239	3399

20583 7590 06/30/2003

PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER	
WORTMAN, DONNA C	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/924,231	Applicant(s) SPEAR ET AL.	
	Examiner Donna C. Wortman, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the c ver sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on June 18, 2003, has been entered.

Claims 1-5 were amended in Paper No. 16 filed June 18, 2003. Claims 1-5 are under examination.

Claim 1, the only independent claim, as last amended is drawn to a composition comprising a polypeptide that comprises the amino acid sequence of a polypeptide that is encoded by a cDNA contained within a plasmid selected from the group consisting of plasmid pBEC580, designated as ATCC No. 97236; plasmid pBEC 10, designated as ATCC No. 97235; plasmid pBL58, and designated as ATCC No. 97237; and a physiologically acceptable diluent. Claim 2 recites that the polypeptide of claim 1 comprises amino acids 1-185 of human HVEM. Claim 3 depends from claim 1 and recites that the polypeptide is soluble, and claim 4 recites that the soluble polypeptide in claim 3 does not comprise a rabbit immunoglobulin heavy chain amino acid sequence. Claim 5 depends from claim 1 and recites that the cDNA comprises nucleotides 294-1142 of SEQ ID NO:1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3 and 4 as last amended are indefinite because they recite, broadly, a polypeptide that is encoded by cDNA contained within any one of three plasmids. Plasmid pBEC 10 encodes and expresses a neo marker; plasmid pBI58 encodes and expresses rabbit Ig heavy chain. As claims 1, 3 and 4 no longer specify an HVEM polypeptide, it is unclear what Applicant intends to claim. Does Applicant intend to claim a composition comprising the neo marker? Does Applicant intend to claim a composition comprising a rabbit Ig heavy chain?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising the HVEM polypeptides as instantly claimed, does not reasonably provide enablement for using compositions comprising those polypeptides as pharmaceutical compositions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to use the invention commensurate in scope with those claims. The claims presently recite compositions comprising a polypeptide and a physiologically acceptable diluent. Interpreting the claims in light of the specification, it is noted that the phrase "physiologically acceptable diluent" appears four times in the specification:

At page 3, lines 1-3; and, all under the heading "V. Pharmaceutical compositions," at page 24, lines 1-2; page 25, lines 1-6; and page 25, lines 10-16. Since "physiologically acceptable diluent" is disclosed only in the context of making and using pharmaceutical compositions, the claims are still interpreted as being drawn to pharmaceutical compositions since pharmaceutical use is the only intended use disclosed for compositions comprising a physiologically acceptable diluent. While the specification discloses the polypeptides themselves, and discloses how to make compositions comprising them and a physiologically acceptable diluent, the specification does not teach one of skill in the art how to use such compositions as a pharmaceutical. The specification does not disclose that there is any beneficial effect as a result of treating with the claimed composition. It is apparent from the disclosure that the pharmaceutical use contemplated is that of a treatment or preventative for human herpesvirus infections. The specification at page 17, lines 18-20, states "... there must be cell surface molecules expressed in human cells, in addition to HVEM, that can be used for entry." This statement would indicate that merely preventing the virus from binding to cell surface HVEM would be insufficient to prevent entry of the virus into human cells *in vivo*. Montgomery et al. (Cell 87:427-436, 1996), published after Applicant's filing date, of record, is cited in this regard. While soluble HVEM:Fc had some ability to block infection in cultured CHO cells expressing recombinant HVEM, for example, Montgomery et al., at page 432, last complete sentence in column 2, pointed out that "The anti-HVEM serum and HVEM:Fc had only marginal ability to block HSV-1 infection of HeLa cells." Thus it is clear that one cannot extrapolate even from one *in vitro*

cultured cell line to another with respect to the ability of HVEM to treat or prevent human herpesvirus infections. Taking into account the state of the art at the time the invention was made, the lack of predictability in the field, and the lack of working examples that can be correlated with any particular therapeutic effect that is obtained as a result of administration of the claimed composition, the specification cannot be said to enable the use of claimed compositions as pharmaceuticals.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,303,336, of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compositions comprising polypeptides encoded by plasmids designated as ATCC No. 97236 and ATCC No. 97237 instantly recited are not distinguished from the HVEM polypeptides as claimed in US Patent No. 6,303,336.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
June 29, 2003